Complementary Alternative Medicine at the NIH



Spring 2000 Volume VII, Number 2

National Center for Complementary & Alternative Medicine Clearinghouse

What's Inside...

A Message from the Director $\underline{2}$

NCCAM Funding Leads to Nation's First Center for Pediatric CAM Research

.3

Personnel Profiles: NCCAM's New Administrators

4

NCCAM's Strategic Plan: Posted for Public Comment

5

NCCAM's Search for a Clinical Director

6

Frequently Asked Questions About Clinical Trials

6

Calendar of Events 10

Shaping the Future of CAM Research: NCCAM's First Town Meeting

"The field of complementary and alternative medicine (CAM) is at an important threshold. The American public wants information about current developments in CAM within a university or hospital setting, not in a marginalized or fringe arena. To help academia and the government address this provocative area, we now must discuss these therapies in an open and informative setting."

David M. Eisenberg, M.D., Director of the Center for Alternative Medicine Research and Education (CAMRE), Beth Israel Deaconess Medical Center, and Assistant Professor of Medicine, Harvard Medical School, both in Boston, Massachusetts, made these remarks at the first town meeting on CAM research.

Stephen E. Straus, M.D., the first permanent director of the National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH), sponsored this town meeting with the CAMRE in Boston on March 15, 2000. The meeting brought medical experts together to discuss current developments in CAM research at the local, regional, and national levels, as well as at the NIH.



David M. Eisenberg, M.D.



Stephen E. Straus, M.D.

A Message from the Director

Several remarkable events have shaped the last few months for me as NCCAM director. The two most prominent ones were our first town meeting on CAM and my testimony before the U.S. Congress to support NCCAM's FY 2001 budget request.

The town meeting was held in conjunction with the Center for Alternative Medicine Research and Education of the Beth Israel Deaconess Medical Center in Boston, Massachusetts. This landmark event brought together health care professionals and the public to discuss major issues in CAM. Enthusiastic participants debated everything from the terminology we use to describe the field to specific treatments, such as acupuncture, massage, and chiropractic.

Before the Congress, I reinforced the need for more rigorous scientific research on CAM, which necessitated a request for an additional \$3 million to raise our budget to more than \$71 million. I am pleased to share with you some of NCCAM's achievements that I summarized for the Congress in my testimony.

Since NCCAM's inception, we have established large, well-designed studies with several other Institutes and Centers of the NIH. For example, the NCCAM co-sponsored rigorous research with the National Institute on Aging on *Ginkgo biloba* for memory loss, the National Institute of Arthritis and Musculoskeletal and Skin Diseases on acupuncture for osteoarthritis, and the National Institute of Mental Health and the Office of Dietary Supplements on St. John's wort for depression.

Also included in our very broad research agenda are studies of

mind-body medicine, such as reducing hypertension through meditation and treating asthma with biofeedback and yoga.

Later this year, we will collaborate with the National Institute of Diabetes and Digestive and Kidney Diseases and other NIH Institutes and Centers to convene a trans-NIH conference on the placebo effect. The goal is to improve our understanding of the mind's healing powers.

We also fund Specialized Research Centers focusing on important public health issues, including addiction, aging, arthritis, cardiovascular disease, chiropractic, neurological disorders, and pediatric diseases. With the addition of two Centers for Dietary Supplement Research: Botanicals in FY 1999 and at least one more Botanical Center in FY 2000, we will likely bring the total number of NCCAM-supported centers to 15 by the end of FY 2000.

As we continue to expand, our focus is on integrating validated CAM therapies into conventional medical practice. To this end, we will create awards to foster the incorporation of CAM information into the curricula of medical and allied health schools and continuing education programs. To attract talented individuals to research and to give them needed, critical, clinical research skills, the NCCAM also established a Clinical Research Curriculum Award.

We recognize that many CAM modalities come from the traditional healing practices of other nations. Because of the international character of CAM, the NCCAM will develop a broad-based international research program. In collaboration with several other NIH Institutes and

Centers, we will support locally-based, traditional, indigenous research projects in countries with the greatest opportunities for promising CAM research. To support this important initiative, we will appoint a director of International and Traditional Medicine Studies.

We also are establishing an Intramural Research Program to coordinate clinical research and train future CAM researchers. We currently are interviewing candidates for the position of director for this program.

Our efforts to give health care providers and the public information about the safety and effectiveness of CAM continue to be successful. For example, our Web site http://nccam.nih.gov averages more than 460,000 hits per month. And, information specialists at our public information clearinghouse respond to about 2,000 CAM-related requests each month.

Americans deserve information that is based on compelling scientific research. I am confident that we are shaping a research agenda that covers all diseases relating to public health and follows demands of the public for reliable scientific information about the safety and effectiveness of CAM modalities.

By supporting information sharing, collaboration, rigorous research, and training, it is our goal that ultimately the term "complementary and alternative medicine" will be superseded by the concept of "integrative medicine."

Stephen E. Straus, M.D.

NCCAM Funding Leads to Nation's First Center for Pediatric CAM Research

With a \$5 million research grant from the NCCAM, the University of Arizona in Tucson drew on two of its strongest areas—pediatric research and integrative medicine—to create the nation's first center for CAM research on pediatric diseases.

The Pediatric Center for Complementary and Alternative Medicine (PCCAM) at the University of Arizona "studies pediatric disorders for which no conventional therapy is available," says Fayez K. Ghishan, M.D., D.C.H., a pediatrician and director of the Steele Memorial Children's Research Center at the university. The Children's Research Center has been designated a Center of Excellence by Arizona's Board of Regents.

Dr. Ghishan oversees the PCCAM along with Andrew Weil, M.D., director of the university's Program in Integrative Medicine, also the first of its kind in the country.

Fighting Childhood Diseases Through CAM Research

The PCCAM already has begun three clinical trials: a randomized, controlled trial of osteopathy and echinacea for recurrent ear infections; a prospective study of osteopathy and acupuncture for cerebral palsy; and an evaluation of relaxation, guided imagery, and chamomile tea for functional abdominal pain.

The PCCAM is accepting proposals for two more research projects. Some of the topics under consideration are acupuncture for depression in adolescents, osteopathic manipulation for asthma, and alternative treatments for cystic fibrosis. Dr. Ghishan firmly believes "randomized clinical trials are the answer" to the many questions about CAM.

Teamwork Is Key

Collaborating researchers come from the Children's Research Center and the Program in Integrative Medicine, as well as the university's College of Pharmacy, Center for Pharmaceutical Economics, Department of Psychology, and Department of Psychiatry.

In addition, practitioners from the Arizona Prevention Center and homeopathic, osteopathic, and Chinese medicine specialists from around the country contribute to the studies. In a true spirit of collaboration, researchers recruit patients from the university and private practices of participating physicians and through the State's Children's Rehabilitative Services facility.

The PCCAM also relies on resources provided by the university's biostatistical, bioenergetic, biopsychosocial, biopharmacological, and biomechanical "core facilities." These facilities support the PCCAM from various areas of the university, such as the Human Energy Systems Laboratory, and by involving researchers with

specific skills, such as biostatistics, hypnosis, and osteopathic medicine.

Dr. Ghishan feels the cooperation among departments, institutions, and researchers is one of the PCCAM's best features. He hopes that other academically-based research centers will consider extending their research to large private practices outside their universities. "We've been aggressive in reaching out to the community," he says. "Many people in our area are aware of the research we're doing, and a number of patients come from among the large medical practices in the community."

Involving the Community

Community support for CAM therapy has benefited the PCCAM greatly. "We have a unique patient population in the Tucson area," says Dr. Ghishan. "About 30 percent of the population is Hispanic American, and about 5 percent is Native American. Both of those groups use a lot of alternative medicines," which



Fayez K. Ghishan, M.D., D.C.H., and a patient at the Pediatric Center for Complementary and Alternative Medicine in Tucson, Arizona

Personnel Profiles: NCCAM's New Administrators

Camille Hoover Named Executive Officer

Camille M. Hoover was appointed NCCAM's first executive officer on March 12, 2000. She serves as an administrative partner and advisor to the director, Stephen E. Straus, M.D., identifying opportunities and leading the design and implementation of innovative business and management systems.

According to Dr. Straus, "It was Camille's energy and effectiveness, and the vision she exhibited in her position within the National Cancer Institute (NCI) that made her such a compelling applicant for the position of NCCAM's first executive officer." He also remarked, "Her vast experience makes her particularly sensitive to human resource and interpersonal issues, as well as providing her with important insights into the patient's perspective and needs in medical research."

Ms. Hoover earned her Bachelors of Arts at the University of Maryland at College Park in 1983, and her Masters of Social Work at the University of Maryland at Baltimore in 1986. She began her career in 1986 as a social worker in the Neuroscience Department of Johns Hopkins Hospital in Baltimore, Maryland.

Two years later in 1988, she joined the NIH Clinical Center as a social worker for NCI's Surgery Branch headed by Steven A. Rosenberg, M.D., Ph.D. In this capacity, she initiated and developed a comprehensive social work program for more than 1,000 patients taking part in study protocols at the Surgery Branch. She also served as a Field Instructor for master's level social work interns and as a member of the NCI Intramural Review Board.

In 1991, Ms. Hoover was selected for the NIH Management Intern Program, providing an opportunity for her to transition from the clinical to administrative arena and to gain experience in many of the diverse NIH professions.

Building on her skills as a social worker, Ms. Hoover expanded her talents by becoming the Administrative Officer for NCI's Surgery Branch in 1992. In 1995, she was promoted to manager of one of NCI's largest Administrative Resource Centers (ARCs). In this position, she was responsible for the administrative leadership and oversight of 29 ARC staff and more than 700 program staff within the Division of Clinical Sciences. Thriving in this challenging environment, she implemented operating policies that helped streamline administrative procedures and improve customer service.

Ms. Hoover's devotion to the needs of the branches and the scientists she supported is well known at the NCI where she has been praised as an exceptional leader and advocate



Camille M. Hoover NCCAM Executive Officer

for the intramural program. Edison T. Liu, M.D., Director of the Division of Clinical Sciences, NCI, remarking on Camille's intensity and understanding said, "She is a cross between Mother Teresa and General Norman Schwartzkopf... a strange but wonderful mix of comfort and command, of gentleness and drive..."

Ms. Hoover's diverse career experiences have offered her unique expertise for her new role as NCCAM's executive officer. "My strengths have evolved from my ability to see things from several perspectives: as a social worker in the hospital room, interacting with patients and their families, doctors, and nurses; as an ARC manager in the 'board room'; and as an administrative officer working for multiple branches over the years," she says. "These perspectives inspire me to move the mission of the NCCAM forward by providing it with the highest standard of administrative service and leadership."

Her goals as executive officer are to establish administrative structures and operational policies to support rigorous science; develop innovative and streamlined methods of doing business; and promote high-quality, consumer-friendly service at all levels of the NCCAM.

Christine Goertz Named New Program Officer

Christine Goertz, a doctor of chiropractic (D.C.) and of health services research, policy, and administration (Ph.D.), is the first chiropractic ever to hold an office at that level within the NIH. "I bring a CAM practitioner's perspective to the position," she says, "as well as a background in research."

Dr. Goertz's areas of concentration are cardiovascular disease, chronic pain, musculoskeletal disease, and health services research. As a program officer at the NCCAM, part of her duties include management of a portfolio of research grants on these and other topics. She also serves as the Developmental Research Coordinator, concentrating on small grants for pilot or feasibility studies in areas where there has not been a lot of research.

"I feel that probably the most important thing that I bring to my position at the NCCAM is a unique perspective that incorporates both the CAM practitioner culture and rigorous training in scientific methods," says Dr. Goertz. "I believe this combination of experience enables me to better understand the dynamics of what occurs when strongly held belief systems and science are asked to sit at the same table together, and I want to assist in making this process work."

Among her goals for the NCCAM is to establish educational and training modules to help CAM practitioners who do research become more skilled and competitive at proposing and winning research grants. "I'd like to see more CAM practitioners doing CAM research," she says. "In the long run, they are the ones who will sustain the research efforts."

Dr. Goertz earned her doctor of chiropractic degree in 1991 from the Northwestern College of Chiropractic in Bloomington, Minnesota, and worked in research and clinical practice at the College's Center for Clinical Studies for 2 years. While pursuing her doctoral degree from the University of Minnesota's School of Public Health, she concentrated on clinical research and was co-Principal Investigator of a randomized clinical trial on treating hyper-

tension with alternative therapies. For 2 years, Dr. Goertz served as the Vice President of Research, Policy, and Information Services for the American Chiropractic Association.



Christine Goertz, D.C., Ph.D. NCCAM Program Officer

Dr. Goertz is a member of the American Chiropractic Association, the American Public Health Association, and the Association for Health Services Research. In 1994, she received the President's Award from the Minnesota Chiropractic Association. She has testified before the U.S. Congress on Health Care Finance Administration policies and before the Minnesota

State Legislature on chiropractic. Dr. Goertz has published numerous research and policy papers and has given presentations around the country on chiropractic and other CAM research and policy considerations.

Because she has direct clinical and research experience with areas being studied in the grants she oversees, Dr. Goertz says, "I have a little different perspective. I'm able to look at the science from the viewpoint of a researcher. I also look at the effect the research may have on patients and practitioners. In many cases, I know where the research holes are and what the priorities are as research relates to clinical practice," she says.

Ms. Hoover and Dr. Goertz bring the professional perspectives of social worker, administrator, researcher, and CAM practitioner to their roles as business and research managers. As is true for all NCCAM staff members, Ms. Hoover and Dr. Goertz are directly linked to NCCAM's mission of generating, and providing the American public with, reliable information about the safety and effectiveness of CAM practices.

NCCAM's Strategic Plan: Posted for Public Comment

As a public health agency that values input from our diverse group of stakeholders, the NCCAM is pleased to provide a draft version of our Strategic Plan, "From Many Traditions: Toward One Medicine," for your review and comment.

The document is posted on our Web site at http://nccam.nih.gov through June 21, 2000.

For your convenience, a form is provided to enable you to submit comments directly to us electronically.

We value your input and look forward to receiving your comments before finalizing the Strategic Plan.

NCCAM's Search for a Clinical Director

The NCCAM is proceeding expeditiously with recruitment of a recognized authority in clinical research to develop a research program integrated with other NIH Institutes and Centers.

To this end, the NCCAM has established a search committee, to be directed by Peter Lipsky, M.D., director of intramural research at NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Lipsky is a noted basic and clinical authority in studies of immunologic disease. He also is an author of numerous studies regarding traditional Chinese medicine as a treatment for arthritis. In addition, the search committee includes members of the CAM community

and two members of NCCAM's Advisory Council.

Program Goals

NCCAM's Intramural Research
Program will be multi-dimensional
in nature and scope, one which will
incorporate alternative medicine
practices, train post-doctoral fellows
and others in CAM-specific study
techniques and methodology,
enhance the quality of alternative
medical care at the NIH, and add to
the cadre of scientists committed
to CAM research.

The intramural program primarily will be a clinical research program involving all phases of clinical studies from natural history and pharmacology, through definitive clinical trials. Laboratory studies will be done collaboratively with other Institutes and Centers of the NIH.

The program will provide a critical mass of CAM research and a focal point of collaboration, to leverage the best capabilities of NIH Institutes and Centers, Federal research partners, and other research institutions. NCCAM intramural investigators will collaborate with colleagues outside the NCCAM on outcomes research; pharmacologic, epidemiological, and field studies; and all phases of intervention trials. The intramural program also will bring CAM practitioners to the NIH campus to participate in NCCAM's research activities.

Frequently Asked Questions About Clinical Trials

What Is a Clinical Trial?

Clinical trials are rigorous research studies in which new treatments drugs, diagnostic procedures, vaccines, medical devices, and other therapies—are tested in people to see if they are safe and effective.

With any new treatment, risks and benefits are possible. Legitimate clinical research is federally regulated, with safeguards built in to protect patients. Doctors and other health professionals run the tests according to strict rules to make sure that participants are treated as safely as possible.

Who Can Take Part in a Clinical Trial?

To study many different diseases and possible treatments, clinical trials include patients and healthy people of all ages. Your ability to take part in a clinical trial is determined by your age, type of disease, medical history, and current medical conditions.

Inclusion and exclusion criteria vary across clinical trials. Before joining a clinical trial, you must qualify for the study by meeting all of its inclusion criteria.

Inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe.

What Is Informed Consent?

Informed consent is the process of learning your rights as a study volunteer and understanding the main facts about a clinical trial before you decide whether or not to participate. It is important to know that you have the right to leave the trial at any

time you choose. In addition, before you can give informed consent, you need to know the following:

- Who is sponsoring and conducting the research?
- Who has reviewed and approved the study?
- What do the researchers want to accomplish?
- Why does the research team think the treatment, drug, or medical device will work?
- What will be done during the trial and for how long?
- What will I be required to do during the trial?
- What are the potential risks and benefits involved in the trial?
- What other treatments are available?

Clinical Trials (Continued from page 6)

What Happens During a Clinical Trial?

The process depends on the kind of trial in which you take part. The research team will include doctors and nurses as well as social workers and other health care professionals. Your health will be checked at the beginning of the trial, you will be given specific instructions for taking part in the trial, you will be monitored carefully during the trial, and the team will stay in touch with you after the study.

Generally, clinical trials take place at research facilities, teaching hospitals, specialized research clinics, or doctors' offices. Some studies involve hospitalized patients; others are done on an outpatient basis.

Participants commonly have to follow strict dosing schedules, keep detailed records of symptoms, periodically give blood samples, and undergo several evaluations over time to assess the effects of the test drug and how the disease is progressing.

In some clinical trials, not all participants will receive the drug being studied. In controlled clinical trials, participants are divided into a test group and a control group for comparison. Members of test and control groups generally are similar in age, health status, and other factors that may affect treatment outcome. The test group may receive varying doses of one or more test compounds. The control group may receive no treatment, treatment with a drug already known to be effective, a combination of test drugs or other interventions, or a placebo. A placebo is a presumably pharmacologically inactive substance.

Participants must be advised of any significant new findings from the

study that might relate to their willingness to continue to take part in the study, such as recently noted toxic effects. If the treatment in a trial is not helping patients or if one treatment is found to be clearly superior to another treatment in the trial, the researchers may choose to halt the trial before it has been completed, particularly if significant adverse events have been reported.

What Are the Benefits and Risks of Participating?

Risks and benefits vary across trials and from person to person. Some risks involved in taking part in a clinical trial are: side effects or adverse (unwanted) reactions to medications or treatments; the treatment may not be effective or safe; and the study protocol (set of rules) may require a lot of your time.

Potential benefits of taking part in a clinical trial include: taking an active role in your own health care; gaining access to new treatments that are not available to the public; obtaining expert medical care at leading health care facilities during the trial; and helping others by contributing to medical research.

Why Are Clinical Trials Important?

Clinical trials are the primary basis for researchers to find out if a promising treatment is safe and effective for people. Clinical trials also tell researchers which treatments are more effective than others.

People take part in clinical trials for many reasons. Usually, patients hope for benefits for themselves. They also may hope for a cure for their disease, a longer time to live, or a way to feel better. Often, they want to contribute to research that may help others.

By taking part in a clinical trial, you may try a new treatment that may or may not be better than those already available. You also may contribute to a better understanding of how the treatment works in people of different ethnic backgrounds and genders.

What CAM Clinical Trials Are Being Conducted?

Currently, CAM practices and procedures are the focus of several clinical trials sponsored by the NIH. For example, NIH's National Cancer Institute (NCI) is studying the prevalence of CAM usage among women at risk for breast cancer.

A study sponsored by the NCCAM, "Ginkgo Biloba Prevention Trial in Older Individuals," will start recruiting patients in Spring 2000. It will be a randomized trial to compare *Ginkgo biloba* to a placebo in healthy men and women, at least 75 years old.

Still another NCCAM-sponsored study, "Acupuncture in the Treatment of Depression," is testing the ability of acupuncture to treat major depression. The study is unique in that treatment effects will be from the perspective of both Western psychiatry and Chinese medicine.

How Do I Locate a Clinical Trial?

The NIH, through the National Library of Medicine (NLM), has developed an online database of clinical research studies http://clinicaltrials.gov. Information about clinical trials currently focusing on CAM, including studies of acupuncture, *Ginkgo biloba*, St. John's wort, and vitamin E, can be found here.

ClinicalTrials.gov currently contains more than 4,000 clinical studies, mostly sponsored by the NIH. But as it grows, it also will include studies by other Federal agencies and by private organizations, such as drug makers.

NCCAM's First Town Meeting (Continued from page 1)

Drs. Straus and Eisenberg spoke to an enthusiastic audience of more than 500 health care professionals and members of the press and general public. The town meeting was held at the conclusion of 5 days of CAMRE-sponsored continuing medical education courses that attracted almost 3,000 national and international participants.

Growing CAM Usage

"There is no consensus as to what to label this field," Dr. Eisenberg said. "CAM therapies are not taught widely at medical schools and are not generally available in U.S. hospitals. However, trends in CAM usage show that the public is increasingly aware of CAM. CAM therapies are routinely used by more than 80 million adults. In 1997, Americans made more than 600 million office visits to CAM providers and spent an estimated \$30 billion on CAM-related treatments and products."

Dr. Eisenberg pointed out that from 1990 to 1997, visits to CAM practitioners increased by 47 percent and expenditures for services increased by 45 percent. Yet, less than 40 percent of CAM users reported using alternative medicine to their conventional health care providers. "This can be particularly dangerous for the estimated 15 million people who use supplements with prescription drugs," Dr. Eisenberg emphasized.

Safeguarding People

The U.S. public is demanding specific information about what works, what practitioners are available, which insurance companies will cover the costs of office visits and treatments, and whether conventional doctors somehow will think less of them for

asking about CAM. To ensure safety, the research and medical communities now must communicate to the public scientific evidence derived from CAM clinical trials.

"The scientific games have begun," said Dr. Eisenberg, "and safety trumps efficacy. We must provide methods to safeguard the public and caregivers." Dr. Eisenberg concluded by describing the collaborative process needed to improve CAM research, education, clinical service, and information resources.

Putting Resources in Place

Dr. Straus emphasized that, "The resources of the scientific community are being harnessed to help shape the future of CAM. How the allocated money is spent is being dictated by the demands of the public."

Dr. Straus pointed to the advantage of working within the NIH, which is first and foremost a research institution. "This is a great public health opportunity," said Dr. Straus in his opening remarks. He noted that NCCAM's priorities are those treatments that show the greatest promise and those likely to affect the most people. "We are turning NIH's approach to research on its head



Town meeting participants during a question and answer session

by starting with studies of people who are using CAM and not the usual route of molecules, mice, and then men as in conventional medicine," said Dr. Straus.

As part of the NIH, NCCAM's mandate is to move the hierarchy of CAM evidence from the realm of anecdote to definitive, large, randomized, double-blind, controlled studies. The scope of investigation of NCCAM's nine research centers across the country revolves around such leading public health problems as dementia, depression, osteoarthritis, and pain. This year alone, the NCCAM will fund approximately 80 CAM studies.

Setting Research Priorities

Dr. Straus briefly outlined the basic NCCAM strategic areas: investing in rigorous research, training people to investigate CAM, expanding outreach efforts, facilitating integration with conventional medicine, and practicing responsible stewardship. Research priorities must focus on the most credible preliminary data and include the simplest study designs. Dr. Straus concluded by emphasizing the need to facilitate the integration of CAM into conventional medicine and find "compelling evidence of safety and efficacy."

Questions from the audience ranged from what areas currently are being investigated by the NCCAM to specifics about the placebo effect and the safety standards of botanicals. Drs. Straus and Eisenberg then turned the meeting over to three CAM practitioners for overviews of their areas of expertise.

Studying Therapeutic Massage

The first presenter to speak was Janet R. Kahn, Ph.D., L.M.T., President, American Massage Therapy Association Foundation, and an NCCAM Advisory Council member. Dr. Kahn described the history of massage therapy and bodywork as an inherently integrative health modality. Dr. Kahn quoted massage therapist and author Deane Juhan by saying, "The skin is no more separate from the brain than the surface of a lake is separate from its depths."

Research findings indicate that massage enhances relaxation, decreases both pain and our perception of pain, reduces anxiety and elevates mood, promotes a sense of well-being, and supports the body's self-healing tendencies. It also may improve worker productivity. It has been used effectively to treat low back pain and lymphedema (swelling due to the buildup of certain fluids in the body) in some patients, such as women recovering from mastectomies. Massage also shows promise in reducing health-related complications for premature infants, as well as improving sleep and easing stress, anxiety, and depression among troubled vouth who are institutionalized.

Dr. Kahn mentioned that, "One way massage therapy fits in an integrative health care system is by making difficult medical procedures more tolerable for patients, such as premature infants."

Dr. Eisenberg added that, "Because massage therapy has shown promise in improving sleep patterns and enhancing well-being and mood in some patients, both Dr. Kahn and I are interested in studying the use of massage and touch therapy in hospice care."

Researching Chiropractic

William C. Meeker, D.C., M.P.H., Director of Research for the Palmer Center for Chiropractic Research at the Palmer College of Chiropractic in Davenport, Iowa, then addressed the audience. He is the Principal Inves-



People visiting the NCCAM Clearinghouse's exhibit at the town meeting

tigator of the Consortial Center for Chiropractic Research, one of NCCAM's research centers; and is a member of NCCAM's Advisory Council.

Chiropractic is an evolving health profession concerned with the diagnosis, treatment, and prevention of disorders of the musculoskeletal system, especially the spine, and the effects of these disorders on the nervous system and general health. It is the third largest doctorate program in U.S. health professions and is the most commonly used CAM provider in the United States.

"We have a respect for the inherent healing ability of the body," said Dr. Meeker. He emphasized that, "There is evidence from randomized controlled studies that spinal adjustment for lower back pain is effective. In 1994, the U.S. Agency for Health Care Policy and Research concluded that spinal manipulation is safe and effective for acute, uncomplicated low back pain."

Chiropractic is used by approximately 10 percent of the American population annually, with 95 percent of patients presenting with pain in the low back, neck, extremity joints, and head. This is a patient-centered,

hands-on approach, with spinal manipulation as its primary intervention. Ten NIH-supported studies encompassing both fundamental and clinical research now are ongoing and focusing on pain syndromes, neurophysiology, and clinical biomechanics.

"The high rate of use of spinal manipulation indicates that it is mainstream on a patient level. But, as a profession, there are various levels of integration with conventional medicine," concluded Dr. Meeker.

Investigating Acupuncture

The final speaker was Ted J. Kaptchuk, O.M.D. (Doctor of Oriental Medicine), Associate Director, CAMRE, and Assistant Professor of Medicine, Harvard Medical School. Speaking about the practice of acupuncture, Dr. Kaptchuk said that, "The radical challenge of acupuncture is that illness and health are totally knowable by the human mind. We don't need to rely on technology, but on the human encounter."

Expanding on this concept, Dr. Kaptchuk said, "The practitioner uses what the person experiences in life to predict treatment. The

NCCAM's First Town Meeting

(Continued from page 9)

acupuncturist interprets the descriptive images of vin and yang to produce a 'weather report' for the person, and then manipulates the images to promote healing."

We are turning NIH's approach to research on its head by starting with studies of people who are using CAM. This is not the usual route of molecules, mice, and then men as in conventional medicine.

Acupuncture has been the subject of extensive clinical research since the seventies. More than 500 randomized controlled trials have been performed. "We need to learn more about how to do acupuncture research. We must refine our methods of research to produce a new way of thinking, generate objective evidence, and ultimately improve our health care system," added Dr. Kaptchuk.

Answering Audience Questions

The presenters then took questions from the audience. Many inquiries focused on the use of herbals and the lack of regulation. Dr. Straus emphasized the need for consumers to shop wisely. The U.S. Food and Drug Administration has active means to deal with safety issues, and oversees the issue of lack of regulation of herbs.

Audience members also asked questions about training opportunities for young scientists. Dr. Eisenberg spoke about

a new 3-year fellowship for training and mentoring internists in CAM at the Harvard Medical School. Issues relating to the challenges of research in this area and its taxonomy were discussed.

Melding Ancient Medicine and New Science

Science with standards set by modern medicine together with, as Dr. Kahn said, "wisdom from the ancient traditions of medicine that can't be measured," all must be integrated.

At a press briefing following the main session, Dr. Straus emphasized, "We want to talk to the community directly. We want to build the trust of the American people to prove we are open to good ideas and also build trust within all aspects of the medical profession. What we must show are results from diligent research. This is ancient medicine, but a new science."

Calendar of Complementary & Alternative Medicine Events

JUNE 2000 ===

9-11 Comprehensive Cancer Care III: Integrating **Complementary & Alternative Therapies**

Sponsor: National Cancer Institute, NCCAM, and

Center for Mind-Body Medicine

Location: Hyatt Regency Crystal City, Arlington, VA Contact: PTF - CCC2000, Conference Registration,

19528 Amaranth Drive,

Phone: 301-353-1807 Fax. 301-353-1808

Web Site: http://www.cmbm.org

Germantown, MD 20874 Contact:

Workshop: Complementary and Alternative Medicine in Cardiovascular, Lung, and Blood

Research

National Heart, Lung, and Blood Institute Sponsor:

(NHLBI) and NCCAM

NLM Lister Hill Auditorium, NIH, Location:

Bethesda, MD

Michael C. Lin, Ph.D., NHLBI; or Contact:

Richard L. Nahin, Ph.D., M.P.H., NCCAM

Phone: 301-435-0560 (Lin) or 301-496-4792 (Nahin)

28-29 Metals in Medicine: Targets, Diagnostics, & Therapeutics

Sponsor: National Institute of General Medical Sciences,

> Center for Scientific Review, National Cancer Institute, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Allergy and Infectious Diseases, National Institute of Environmental Health Sciences, and Office of Dietary Supplements

Natcher Conference Center, NIH, Bethesda, MD Location:

Dr. Peter C. Preusch Phone: 301-480-2802

Web Site: http://pub.nigms.nih.gov/mim

AUGUST 2000 =

National Advisory Council on Complementary 28-29 and Alternative Medicine (NACCAM)

Sponsor: NCCAM

NIH Neuroscience Office Building, Conference Location:

Room C, 6001 Executive Blvd., Rockville, MD

Contact: NCCAM Phone: 301-435-5042

Future NACCAM Meeting Dates:

November 13-14, 2000 February 5-6, 2001 May 31-June 1, 2001

August 27-28, 2001

January 14-15, 2002 May 6-7, 2002 August 26-27, 2002

12

Pediatric CAM Research (Continued from page 3)

means CAM already has established a foothold in the area. "Here, it's easy for doctors to convince patients to use alternative medicine; there's a great deal of enthusiasm for it," says Dr. Ghishan.

Because the PCCAM focuses on childhood illnesses that do not respond well to conventional therapies, Dr. Ghishan says, "Parents are hungry for alternative treatments for their children." In fact, he says, "One of our problems is finding controls for our studies, especially for abdominal pain, because parents don't want their children to be in the control group. When their child is in pain, they don't want to wait for effective treatments."

Research Challenges

For the study on abdominal pain, Dr. Ghishan says the control group learns relaxation techniques but, for comparison purposes, does not learn guided imagery. The need for placebos and control groups continues to pose a challenge in other studies as well. For example, the university's Department of Pharmacy currently is working on a suitable placebo for chamomile tea. For the osteopathic studies, the control group receives an examination that is designed to "appear to be" a treatment.

Integrative Medicine Education

As another function of the NCCAM grant, the university has established two fellowships for physicians in pediatric CAM research. These individuals work with other research fellows of the Program in Integrative Medicine. John Mark, M.D., a pediatric pulmonologist, and Sharon McDonough-Means, M.D., a developmental/behavioral pediatrician, are

the first to take part. Two more candidates will join the program this summer.

"The fellowship is distinctive because of its overlap with the Program in Integrative Medicine, which is unique to the university," says Tracy Gaudet, executive director of the program. "Participants receive education and exposure to resources they would not get elsewhere, such as an 8-week orientation in different CAM modalities. They even take part as patients in some training."

Each fellow is assigned to work on one of the grant research projects. "In addition, fellows can participate in the Program in Integrative Medicine's educational curriculum, which includes instruction in healing, mind-body medicine, and spiritual medicine, among other training topics," says Ms. Gaudet.

Ms. Gaudet believes physicians who are trained in mainstream medical institutions simply do not know what questions to ask about alternative medicine or how to research it. "My hope is that participants will learn to ask the right questions and that they'll go back into academic situations with 2 years of research in this domain," says Ms. Gaudet.

To further its goal of educating more physicians about integrative medicine, the PCCAM sponsored the first annual Pediatric Integrative Medicine Conference in Tucson in February 2000. More than 300 pediatricians and other health care professionals from around the world attended the 3-day conference.

Encouraging CAM Research

Dr. Ghishan attributes much of the PCCAM's success to his colleagues. "Dr. Weil's presence has generated incredible excitement for alternative medicine in Arizona," he says. "Dr. Weil was the first to establish alternative medicine training for

physicians. Also, James E. Dalen, M.D., dean of the university's College of Medicine, has been a great supporter of alternative medicine."

The PCCAM is among the first research centers funded by the NCCAM to evaluate alternative treatments for chronic health conditions. Each Center is designed to efficiently evaluate promising alternative medical practices by establishing mechanisms for investigators to have their research ideas reviewed, developed, and executed in a scientifically rigorous manner.

For more information about NCCAM-sponsored CAM research centers, call the NCCAM Clearinghouse toll-free at 1-888-644-6226. △

Clinical Trials (Continued from page 7)

In addition, the NCI and other NIH Institutes and Centers list cancer-related clinical trials at its Web site http://cancertrials.nci.nih.gov. Information specifically on the status of CAM and cancer clinical trials can be located at http://cancernet.nci.nih.gov/treatment/cam.shtml.

If you don't have direct access to the Internet, your local library may be able to help you get information online.

Where Can I Get More Information?

Choosing to take part in a clinical trial is an important personal decision. You may wish to talk with your health care provider.

For more information about CAM research, visit NCCAM's Web site http://nccam.nih.gov, or call the NCCAM Clearinghouse toll-free at 1-888-644-6226.

Complementary & Alternative Medicine at the NIH

is published by the NCCAM, Building 31, Room 5B-37, NIH, Bethesda, MD 20892. NCCAM's director is Stephen E. Straus, M.D. The newsletter is available on NCCAM's Web site http://nccam.nih.gov or via e-mail by contacting the NCCAM Clearinghouse by toll-free telephone (1-888-644-6226) or by e-mail (nccamc@altmedinfo.org). Please specify if you want Adobe Acrobat or plain HTML.

NCCAM's purpose is to facilitate the evaluation of complementary and alternative medicine (CAM) treatment modalities to determine their safety and effectiveness. The NCCAM does not serve as a referral agency for various alternative medical treatments or individual practitioners.

NCCAM's mission is to conduct and support basic and applied research and training and to generate and disseminate information about CAM to practitioners and the public.

NCCAM's Web site is at http://nccam.nih.gov>.

NCCAM's Clearinghouse: For information about the NCCAM or any aspect of CAM, call the NCCAM Clearinghouse at its toll-free number, 1-888-644-6226, between 8:30 a.m. and 5:00 p.m., Eastern time,

Monday through Friday. (Hearing- or speech-impaired callers may dial the same number, and an information specialist will connect the caller to TTY equipment.)

NCCAM Clearinghouse P.O. Box 8218 Silver Spring, MD 20907-8218

1-888-644-6226 (Toll-Free, TTY/TDY, and Fax-On-Demand) 1-301-495-4957 (Fax) nccamc@altmedinfo.org (E-Mail)

This publication is not copyrighted.

New, Free Publication Available

A new publication is available from NCCAM's Clearinghouse:

• Hepatitis C: Treatment Alternatives (Z-04), 8 pages, describes studies of use of milk thistle, licorice root, ginseng, ginger, and St. John's wort in patients with hepatitis C and related liver disorders.

For your free copy, call the NCCAM Clearinghouse's toll-free number: 1-888-644-6226.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service National Institutes of Health Building 31, 5B-37 Bethesda, MD 20892

Official Business
Penalty for Private Use \$300

FIRST CLASS MAIL POSTAGE AND FEES PAID DHHS/NIH Permit No. G-802